Opening Statement of the Honorable Diana DeGette Subcommittee on Health Roundtable on 21st Century Cures September 10, 2014

(As Prepared for Delivery)

Thank you Chairman Upton. And welcome to the participants of the roundtable.

I want especially thank Secretary Burwell for attending this morning. And, of course, Dr. Dan Theodorescu from the University of Colorado Cancer Center.

As you all know, the Chairman and I have worked together to host a series of roundtables and a number of hearings on our 21st Century Cures initiative. We have also sought feedback through white papers and meetings with many interested constituencies. These forums have already proven to have potential to positively impact biomedical research and innovation.

Over the August recess, Members also held a number of very interesting roundtable discussions in their districts. There were events in New Jersey, Florida, Massachusetts, Pennsylvania, Florida, and Illinois. Members are also working on continuing the conversation in September and October in their districts.

I also took 21st Century Cures to Colorado. Just last week, I hosted a roundtable discussion in Denver. We had a vibrant discussion among the panelists on personalized medicine, as well as active engagement and interest from the audience. Hearing from NIH, FDA, local universities and health centers, as well as industry and researchers – we were able to identify some areas where new policy may be helpful to streamline processes.

For example, we discussed the potential time- and cost-savings of a centralized IRB process – something that I have been working on for a long time. We also talked about the importance of data and information sharing among clinical registries. As we all know, however, these are just a few examples of some of the topics that fall under the 21st Century Cures umbrella.

Today, we are looking for feedback from the participants on what we have learned so far. As we have approached this process with open minds and sought guidance from all interested parties, some common themes have emerged. These, of course, do not represent every area where policy solutions could be considered, but are the most commonly identified. These topics include:

- 1. Modernizing clinical trials;
- 2. Facilitating data collection/data sharing;
- 3. Incentivizing drugs/devices for unmet needs;
- 4. Incorporating the patient perspective into research/regulatory process; and
- 5. Developing young emerging scientists.

With the expertise we have here today, I am looking forward to learning more about how we can make a positive difference in these areas. We are asking for small and large ideas – but are also seeking specific policy ideas.

Mr. Chairman, I want to thank all of the participants for being here today. We appreciate their time and dedication to these important issues. Thank you.

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